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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,562	06/24/2003	Michael N. Alekshun	PAZ-190	8041
959	7590	09/08/2006	EXAMINER	
LAHIVE & COCKFIELD 28 STATE STREET BOSTON, MA 02109			SRIVASTAVA, KAILASH C	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/602,562	<b>Applicant(s)</b> ALEKSHUN ET AL.	
	<b>Examiner</b> Dr. Kailash C. Srivastava	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 7-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>06/05/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

1. Applicant's response filed 30 May 2006 to Office Action mailed 29 November 2005 is acknowledged and entered.
2. Labeling each page of the response referred above with Serial Number of the Non-Provisional U.S. Application and Attorney Docket Number is greatly appreciated. This practice in and of itself immensely ameliorates the chances of papers lost during transaction/ transmission of paper once a filing/response arrives at the United States Patent and Trademark Office (i.e., USPTO). However, after a response/filing arrives at the USPTO, the claims, remarks, amendments etc., are separated for proper coding to scan them in the electronic file wrapper (i.e., IFW). In order to ensure that all the papers pertaining to a particular application are properly coded and placed in the same application electronic file wrapper, and to further facilitate the prosecution; especially during a telephonic conversation/ interview with applicant/applicants' representative, inclusion of following information in the header of the each page for any filing/response/amendment, the following information in addition to labeling the header of each and every page of the response with U.S. Non-provisional application Serial Number (i.e., USSN) and attorney docket number is suggested:
  - a. Filing date for said application;
  - b. First Applicant's name;
  - c. Group Art Unit Number (e.g., 1655);
  - d. Examiner's name (e.g., Dr. Kailash C. Srivastava); and
  - e. Date of the Office Action being responded to; and
  - f. the date response is being made.

Papers/responses filed according to above-stated guidelines immensely ameliorate the chances of papers lost during transaction/transmission, coding, indexing and placing the papers in IFW.

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### Claims Status

3. Claim 52 has been added.
4. Claims 1, 11 and 15 have been Amended.
5. Claims 1-52 are pending.

### Restriction/Election

6. Applicants' election with traverse of Group I, Claims 1-6 filed 30 May 2006 to Office Action mailed 29 November 2005 is acknowledged and entered. Applicant's traversal is on the grounds that applicants have presented a new claim, claim 52 and in light of said Claim 52 the restriction requirement in Office Action cited *supra* is improper because said Claim 52 "embraces the species of preventing infections in a subject, treating a microbial infection in q subject and treating specific types of infections in a subject".

Applicants arguments have been fully and carefully considered, however these arguments are not persuasive for the reasons of record at item 3-4, pages 2-4 of the Office Action cited *supra* and for the additional reasons discussed *infra*. However, based on applicants' arguments, Newly presented claim 52 will be considered along with Claims 1-6 in invention of Group I.

Each of the inventions in Groups I-XIII are distinguishable from other because they are drawn to a method having different steps to treat a certain condition or to prevent a certain condition. Furthermore, the instant application is being prosecuted under 35 U.S.C. §111. Applicants are therefore, reminded that one application one invention rule is applied. In addition, the search for each of the distinct inventions of Groups I-XIII is not co-extensive particularly with regard to the literature search because the search strategy for each group requires different considerations than those required for other. In addition, the burden lies not only in the search of U.S. patents, burden also lies in the search

- for scientific and technical non-patent literature;
- foreign patents;

- examination of the claim language; and
- examination of specification for compliance with the statutes concerning new matter, distinctness and scope of enablement.

Clearly different searches and issues are involved with each group. Moreover, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the condition for patentability is different in each case. For these reasons, the restriction requirement is still deemed proper, is adhered to and is made FINAL.

7. Accordingly, Claims 7-51 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR §1.142(b) and MPEP § 821.03. Examiner suggests that the non-elected claims (i.e., Claims 7-51) cited *supra* be canceled in response to this Office action to expedite prosecution.

#### **Priority**

8. Applicants' claim for domestic priority under 35 U.S.C. § 119(e) to 60/391,345, filed 24 June 2002; 60/421, 218 filed 25 October 2002; 60/429,142 filed 26 November 2002 and 60/458, 935 filed 31 March 2003 is acknowledged.

#### **RELEVANT ART**

9. The relevant art made of record and not relied upon is considered pertinent to Applicants' disclosure.

- Alekshun et al., U.S. Patent Application Publication US 2006/0160799 published 20 July 2006
- Alekshun et al., U.S. Patent 7,075,582 B2 issued 11 July 2006.

#### **Claim Rejections - 35 U.S.C. § 112**

10. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

11. Claims 1-6 and 52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled that the inventor(s), at the time the application was filed, had possession of the claimed invention. From the record of the present written disclosure, the scope of the claimed invention recited in claims 1-6 and 52 taken together is not supported by the specification on record.

The specification as currently presented while describing the treatment of a microbial infection via administering a modulator of a transcription factor to an individual in need thereof does not provide support for a method to prevent said infecting in said individual.

Inventions targeted for human therapy claiming method(s) of treatment and/or prevention of a certain ailment bear a heavy responsibility to provide supporting evidence because of the unpredictability of the biological responses to therapeutic treatments. THE STANDARD OF ENABLEMENT IS HIGHER FOR SUCH INVENTIONS because effective treatment and/or prevention or prophylaxis of disease conditions are relatively rare, and may be unbelievable in the absence of supporting evidence. Claims drawn to pharmaceutically acceptable compositions and to methods of administering compounds to human that would in effect “prevent” the condition/ailment from happening require supporting evidence because of the unpredictability in biological responses to therapeutic treatments or therapeutic prophylaxis. In order to enable the skilled artisan to practice the invention as claimed, applicants would have to demonstrate the functional effect and describe the therapeutic effect or prophylactic effect, and describe the effective amounts of each ingredient of the composition for the administration of the composition intended for a method of therapeutic treatment or prophylaxis. there is no guidance in the specification, other than a method to administer a modulator of a transcription factor to an individual in need thereof. moreover, the instant application does not provide a working example providing data that shows that the method of the instantly claimed invention would indeed prevent an event such as the claim designated disease conditions. thus, applicants have not demonstrated the claimed functional effect of preventing “infection of a subject by a microbe

comprising administering a compound that modulates the expression or activity of a microbial transcription factor to a subject" in need thereof.

A person of skill would not be able to practice the claimed invention in a 96-well plate due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Undue experimentation will be necessary because there is no recited guidance, example or teaching in the specification to obtain the instantly claimed prevention of the microbial infection.


### Conclusion

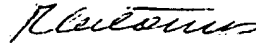
12. For reasons aforementioned, no Claims are allowed.

13 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:30 A.M. to 5:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

  
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Patent Examiner  
Art Unit 1655  
(571) 272-0923  
September 5, 2006

  
RALPH GITOMER  
PRIMARY EXAMINER  
GROUP 1200